UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of

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CAMEO DIAGNOSTIC CENTRE, INC. SPRINGFIELD, MASSACHUSETTS

Docket No. 030-29567-CivP ASLBP No. 94-686-01-CivP

(Byproduct/Source Material License No. 20-27908-01)

NRC STAFF RESPONSE TO BOARD QUESTION REGARDING 10 C.F.R. § 30.9(a)

INTRODUCTION

The NRC Staff (Staff) hereby responds to the order of the Atomic Safety and Licensing Board (Board) requiring the Staff to brief a question the Board posed during the February 1, 1994 prehearing conference. Tr. 15.

BACKGROUND

On November 24, 1993, the Staff issued an "Order Imposing a Civil Monetary Penalty -\$1,750" (Order) to Cameo Diagnostic Centre, Inc., (Licensee). 58 Fed. Reg. 64341 (December 6, 1993). On December 17, 1993, the Licensee requested a hearing on the Order, and on December 30, 1993, a Board was established to preside in this proceeding. 59 Fed. Reg. 1039 (January 7, 1994). On February 1, 1994, the Board held a prehearing conference by telephone and ordered the Staff, among other things, to prepare a brief addressing whether, as a matter of law, a licensee's total failure to provide material information to the Commission can constitute a violation of 10 C.F.R. § 30.9(a). The Board directed the Staff to prepare its answer by February 15, 1994, and required the Licensee to respond to the Staff's filing by March 1, 1994.

DISCUSSION

A licensee's failure to provide material information to the Commission, without more, cannot constitute a violation of 10 C.F.R. § 30.9(a). The Commission's Statements of Consideration pertaining to 10 C.F.R. § 30.9, state that omitted information "which causes an affirmative statement to be materially incomplete or inaccurate" will constitute a violation of 10 C.F.R. § 30.9. *Completeness and Accuracy of Information*, 52 Fed. Reg. 49362, 49366 (December 31, 1987). Thus, it was not contemplated that total omissions, in and of themselves, would constitute violations of 10 C.F.R. § 30.9(a), although such omissions, in certain circumstances, may constitute violations of other Commission regulations.¹

In connection with the preparation of this response, the Staff has determined that violation I.B., as stated in the Notice of Violation and Proposed Imposition of Civil Penalty, did not correctly identify the nature of the regulatory violation. In light of this determination, the Staff has modified both the Notice of Violation and the Order Imposing a Civil Monetary Penalty with respect to violation I.B. to accurately reflect the nature of the violation.² A copy of the modified document is attached hereto as Attachment 1. The modification states that the

¹ For example, the Commission's regulations at 10 C.F.R. § 30.9(b), require licensees to notify the Commission of information they have identified having a significant implication for public health and safety or common defense and security. In addition, licensees must report various events involving licensed material to the Commission. 10 C.F.R. § 30.50.

² The modified order supersedes the Order issued on November 24, 1993. The Staff notes that, pursuant to 10 C.F.R. §§ 2.717(b) and 2.718 of the Commission's regulations, the Board has the authority to modify the modified order as appropriate for the purpose of the proceeding.

Licensee provided the Commission with an inaccurate statement in answer to a question asked by the Staff during a telephone call on November 12, 1992. The modification raises an issue of fact as to whether the information provided was inaccurate or incomplete in a material respect. The Staff considers the Licensee's December 17, 1993 "Request for an Enforcement Hearing" as sufficient to request a hearing with respect to the modified order. The Staff recommends that the Licensee be given 20 days from the date of the modified order to answer the order, as is required by 10 C.F.R. § 2.202.

CONCLUSION

For the reasons set forth above, the Staff agrees that a failure to provide information to the Commission, without more, cannot constitute a violation of 10 C.F.R. § 30.9(a). Additionally, the Staff has modified the Notice of Violation and Order to properly identify the regulatory violation which occurred in this case.

Respectfully submitted,

Catherine & marco

Catherine L. Marco Counsel for NRC Staff

Dated at Rockville, Maryland this 15th day of February, 1994



UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20655-0001

FEB 1 5 1994

Docket No. 030-29567 License No. 20-27908-01 EA 94-035

Cameo Diagnostic Centre, Inc. ATTN: Faul Rosenbaum, President Suite 102 155 Maple Street Springfield, Massachusetts 011005

Dear Mr. Rosenbaum:

SUBJECT: ORDER MODIFYING ORDER IMPOSING CIVIL MONETARY PENALTY - \$1,750

This refers to the Order Imposing Civil Monetary Penalty issued to you on November 24, 1993 (EA 93-005) (Order). The Order imposed a civil penalty of \$1,750 for violations set forth in a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) issued to you on April 16, 1993. By letter dated December 17, 1993, you requested a hearing on that Order. On February 1, 1994, the Atomic Safety and Licensing Board (ASLB) designated to preside in this proceeding held a prehearing conference.

Violation I.B., as set forth in the Notice and referenced in the Order, cited you for being in violation of 10 CFR 30.9(a) for a failure to provide to the Commission information that was complete and accurate in all material respects.

During the February 1, 1994 prehearing conference, the ASLB ordered the NRC staff, among other things, to prepare a brief addressing whether a total failure to provide material information to the Commission can, as a matter of law, constitute a violation of 10 CFR 30.9(a). The staff will be separately filing its brief on the ASLB's question. The NRC staff has reconsidered whether Violation I.B. as stated in the Notice fully reflected the facts of this case. After reviewing the facts, and statements made by the inspector and you, the NRC staff is modifying Violation I.B for reasons stated in Section III of the enclosed Order.

You will need to respond to this modified Order within 20 days of the date of this Order by either requesting that the NRC proceed with the Licensee's December 17, 1993 request for a hearing or by withdrawing the Licensee's hearing request. The response to this Order shall be addressed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, Cameo Diagnostic Centre, Inc.

D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Sincerely,

Hugh L. Thompson, Sr. Depity Executive Director for Nuclear Materials Safety, Safeguards and Operations Support

Enclosure: As Stated

cc w/encls: Department of Public Health Robert M. Hallisey, Director Radiation Control Program 305 South Street, 7th Floor Jamaica Plain, MA 02130

UNITED STATES NUCLEAR REGULATORY COMMISSION

In the Matter of

CAMEO DIAGNOSTIC CENTRE, INC. Springfield, Massachusetts Docket No. 030-29567 License No. 20-27908-01 EA 94-035

ORDER MODIFYING ORDER IMPOSING CIVIL MONETARY PENALTY

I

Cameo Diagnostic Centre, Inc. (Licensee) is the holder of a Byproduct Material License No. 20-27908-01 (License) originally issued by the Nuclear Regulatory Commission (NRC or Commission) on January 30, 1987. The License authorizes the Licensee to perform diagnostic procedures with radioactive byproduct material and to store Promethium-147, in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on December 29, 1992. During the inspection, nine violations of NRC requirements were identified. A Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated April 16, 1993. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice on June 11 and July 23, 1993. In its response, the Licensee objected to the characterization of Violations I.A and I.B as "willful", and to the classification of these violations at Severity Level III; protested the civil penalty assessed for Violations I.A and I.B; and requested remission of that penalty.

After consideration of the Licensee's response and the statements of fact, explanation, and argument contained therein, the NRC staff determined that the violations occurred as stated in the Notice, the Severity Level classification was appropriate, and the penalty proposed for Violations I.A and I.B should be imposed. Accordingly, the NRC issued an Order Imposing A Civil Monetary Penalty - \$1,750 on November 24, 1993. The Licensee responded in a letter dated December 17, 1993 and requested a hearing. On February 1, 1994, the Atomic Safety and Licensing Board (ASLB) designated to preside in this proceeding held a prehearing conference.

Violation I.B., as set forth in the Notice, cited the Licensee against 10 CFR 30.9(a) for a failure to provide to the Commission information that was complete and accurate in all material respects. During the February 1, 1994 prehearing conference, the ASLB ordered the Staff, among other things, to prepare a brief addressing whether a total failure to provide material information to the Commission can, as a matter of law, constitute a violation of 10 CFR 30.9(a).

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The NRC staff has reconsidered whether Violation I.B. as stated in the Notice fully reflected the facts of this case. The original citation for Violation I.B. did not assert that a statement of the Licensee was inaccurate or incomplete, but rather, that the Licensee's omission constituted a violation of 10 CFR 30.9(a). After reevaluating the facts of this case, and statements made by the inspector and the Licensee, the staff is modifying Violation I.B based on an inaccurate statement made by the Licensee in answer to a question asked during a telephone call on November 12, 1992. This statement was confirmed in a letter issued the next day on November 13, 1992. Thereafter, during calls on November 19 and 25, 1992 the staff reiterated the need to obtain a license amendment before possessing material at the new location. However, the licensee did not correct the staff's understanding after receipt of the letter or during the November 19 and 25, 1992 telephone calls.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended, (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT VIOLATION I.B OF THE NOTICE AND ORDER BE MODIFIED TO READ:

III

- 3 -

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

Contrary to the above, the Licensee did not provide to the Commission information that was complete and accurate in all material respects. Specifically, during a November 12, 1992 telephone conversation in response to a question from Region I as to whether the Licensee had licensed materials at its new address (155 Maple Street, Springfield, MA), the Licensee responded negatively. The licensee response was confirmed in a letter from NRC to the licensee dated November 13, 1992 which stated that it was the NRC "understanding that: ... 2. You [licensee] do not as yet possess any licensed radioactive material at this new facility." Therefore, the Licensee provided inaccurate information to the Commission in that it had possessed licensed materials at its new address. This information was material because, had the correct information been known, it would have resulted in action by the NRC to prohibit licensed activity at the new address until a license amendment had been granted.

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The Licensee shall respond to this modified Order within 20 days of the date of this Order by requesting that the NRC proceed with the Licensee's December 17, 1993 request for a hearing or by withdrawing its hearing request. The response to this Order shall be addressed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Atomic Safety and Licensing Board presiding over the proceeding on the December 13, 1993 hearing request and Counsel for the NRC staff in that proceeding at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If the Licensee withdraws its request for a hearing, payment of the civil penalty shall be made within 30 days of the date of this Order. If full payment of the civil penalty has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event that the Licensee requests proceeding with a hearing as provided above, the issues to be considered at such hearing shall be:

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- (a) whether the Licensee was in violation of the
 Commission's requirements as set forth in Violation
 I.A. of the Notice referenced in Section II above and
 Violation I.B. as modified in Section IV above, and
- (b) whether, on the basis of such violations, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, JR.

Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support

Dated at Rockville, Maryland this 15th day of February 1994

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD '94 FEB 16 P4:19

In the Matter of)	
CAMEO DIAGNOSTIC CENTRE, INC. SPRINGFIELD, MASSACHUSETTS)))	Docket No. 030-29567-CivP
Station mass, massiver as)	ASLBP No. 94-686-01-CivP
(Byproduct/Source Material License No. 20-27908-01))	

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSE TO BOARD QUESTION REGARDING 10 C.F.R. § 30.9(a)" of Catherine L. Marco in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system this 15th day of February, 1994:

Judge Ivan W. Smith, Board Chairman* Atomic Safety and Licensing Board U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dr. Richard F. Cole* Administrative Judge Atomic Safety and Licensing Board U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dr. Charles N. Kelber* Administrative Judge Atomic Safety and Licensing Board U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Mr. Paul J. Rosenbaum Cameo Diagnostic Centre, Inc. 155 Maple Street Springfield, MA 01105 Adjudicatory File (2)* Atomic Safety and Licensing Board U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Office of the Secretary (2)* U.S. Nuclear Regulatory Commission Washington, D.C. 20555 Attn: Docketing and Service Section

Atomic Safety and Licensing Board Panel (1)* U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Office of Commission Appellate Adjudication (1)* U.S. Nuclear Regulatory Commission Washington, D.C. 20555

atherine & Marco

Catherine L. Marco Counsel for NRC Staff